

**IN THE UNITED STATES DISTRICT COURT FOR THE  
MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION**

RUTH SMITH, Individually and as Widow for the )  
Use and Benefit of Herself and the Next Kin of )  
Richard Smith, Deceased, )  
  )  
Plaintiff,   ) Civil No. 3:05-0444  
  ) Judge Aleta A. Trauger  
v.    ) (Dist. Of MA No.  
PFIZER, INC., *et al.*,                                   ) 1:05-cv-11515PBS)  
  )  
Defendants.    )

**MEMORANDUM OF LAW IN SUPPORT OF  
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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## **PRELIMINARY STATEMENT**

Plaintiff Ruth Smith alleges that her husband, Richard Smith, committed suicide at the age of 79, after years of chronic pain and depression, because of one prescription of Neurontin, an FDA-approved medication manufactured by Pfizer and prescribed to Mr. Smith by his doctors to treat his pain. Plaintiff filed her Original Complaint in Tennessee state court on May 4, 2005, asserting claims against Pfizer under theories of strict liability, negligence, express and implied warranty, consumer protection, and fraud, including fraudulent concealment. After the case was removed to federal court, it was transferred to the *In re Neurontin Marketing, Sales Practices, & Products Liability Litigation Multi-District Litigation* (“MDL”) in the District of Massachusetts for consolidated pre-trial proceedings.

Pfizer moved for summary judgment in the MDL court arguing, *inter alia*, that Plaintiff could not establish proximate or legal causation for any of her claims. Judge Saris granted Pfizer’s motion with respect to Plaintiff’s express warranty, consumer protection, and fraud claims and denied the motion with respect to Pfizer’s *Daubert* challenge of Plaintiff’s experts on specific causation. See *In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 1629, [05-11515 Dkt. No. 10] at 2 (D. Mass. Aug. 14, 2009). However, Judge Saris did not reach the following issues, finding that these were “fact-specific inquiries involving questions of Tennessee law” that were “best left for the transferor court in Tennessee to resolve”: (1) Whether summary judgment should be granted because “Plaintiff cannot demonstrate that Mr. Smith ingested Neurontin at any time temporally related to his suicide,” and (2) whether summary judgment should be granted because “Plaintiff cannot demonstrate that any allegedly inadequate warnings proximately caused Mr. Smith’s suicide.” (*Id.* at 1-2.) Judge Saris also did not rule on Plaintiff’s implied warranty and fraudulent concealment claims, finding that they also involved questions of Tennessee law. (*Id.*)

On October 22, 2009, the Judicial Panel on Multidistrict Litigation entered a conditional order of remand directing that this case be remanded to this Court for trial. The order became

final on November 6, 2009. Pfizer now seeks summary judgment on these state-law issues against Plaintiff's remaining claims.

Each of Plaintiff's remaining causes of action depends upon Plaintiff's assertion that Neurontin presents a risk of suicide that was not, and should have been, indicated on its warning label. Although Pfizer denies that Neurontin is associated with suicide, the Court need not reach this issue to decide this motion. Plaintiff's claims fail regardless of whether Plaintiff is able to prove *general* causation because Plaintiff cannot meet her burden of proof as to *specific* causation. Plaintiff has no evidence that the absence of a suicide warning (which Pfizer contends was not required) on Neurontin factually or proximately caused her husband's death. This failure of proof requires that all of her claims against Pfizer be dismissed.

First, Plaintiff cannot prove cause-in-fact because she has no evidence that the decedent actually ingested Neurontin shortly before his suicide. Neurontin remains in an individual's system for less than 24 hours, but Plaintiff has no evidence that the decedent consumed Neurontin within even four days of committing suicide. In fact, Plaintiff has no evidence that the decedent consumed Neurontin at any time in particular.

Second, to prove causation under the learned intermediary rule, Plaintiff must put forth affirmative evidence that a different warning to her husband's physician would have changed the physician's decision to prescribe Neurontin. However, Mr. Smith's prescribing physician did not testify that he would not have prescribed Neurontin to the decedent even if the label had warned of the risk of suicide – to the contrary, he still prescribes Neurontin to his patients.

Third, even if Plaintiff had some evidence of cause-in-fact (and she does not), she cannot establish proximate cause. It is well-settled in Tennessee that an individual's decision to commit suicide is an "independent intervening cause" that breaks the chain of causation as a matter of law. This legal rule is subject only to three narrow exceptions, none of which is applicable here.

Finally, Plaintiff's implied warranty and fraudulent concealment claims fail for additional reasons. Plaintiff's implied warranty claim fails because it is undisputed that Plaintiff did not provide Pfizer with pre-suit notice of alleged breach, as required for such claims. Moreover,

Plaintiff's claims for breach of the implied warranty of fitness fail because there is no evidence that Mr. Smith relied on any representations by Pfizer in using Neurontin. Additionally, Plaintiff's fraudulent concealment claims fail because Plaintiffs cannot establish that Pfizer had any duty to disclose, which is an essential element of such claims. Accordingly, Pfizer is entitled to summary judgment on all of the claims in Plaintiff's Amended Complaint.

### **FACTUAL BACKGROUND**

Mr. Smith committed suicide on May 13, 2004, at the age of 79. During his life, Mr. Smith suffered from many well-established suicide risk factors, including chronic pain, depression, hopelessness, and suicidal ideation. These risks were present in his life years before he ever filled his one prescription for Neurontin, a medication approved by the FDA to treat epilepsy and pain associated with post-herpetic neuralgia.

For more than ten years prior to his death, Mr. Smith suffered from chronic joint and spine abnormalities that caused him severe pain and required numerous replacement surgeries. (Cato Dep. [MDL 1644-2] at 23:17-24:2; Jacobs Report [MDL 1644-13] at 12-14.) The severe, unrelenting, chronic pain experienced by Mr. Smith continued up until his suicide. (Trimble Dep. (12/4/09 Cheffo Decl., Exhibit 1) at 446:15-19.) In May 2003, after undergoing spinal surgery, Mr. Smith stated that he "wished he could die because of pain and depression." (Maris Dep. [MDL 1644-4] at 607:13-608:18.) He was then diagnosed with anxiety and depression and treated with Lexapro, an anti-depressant. (Jacobs Report at 11; Cato Dep. at 56:13-25, 62:3-6; Maris Dep. at 554:10-25, 555:3-8, 586:17-23.) Mr. Smith was twice referred for psychological evaluations, but he did not heed these referrals. (Maris Dep. at 608:19-22, 670:22-671:19; Ruth Smith Dep. [MDL 1644-5] at 135:21-25; McCombs Dep. [MDL 1644-6] at 17:7-19.) According to Mr. Smith's daughter, Mr. Smith again contemplated suicide on March 1, 2004. (Satterfield Dep. [MDL 1644-7] at 26:9-27:6; Maris Dep. at 583:8-584:10.) Mr. Smith started to have trouble sleeping because of his increasing pain, and the Smiths began sleeping in separate bedrooms because of his restlessness. (Maris Dep. at 669:6-13.)

To treat Mr. Smith's chronic pain, Dr. Edward Mackey gave Mr. Smith a thirty-day prescription for Neurontin on March 9, 2004. This was the only Neurontin prescription Mr. Smith ever filled. (Pls. Resp. to Defs. 1st Set of Interrogatories [MDL 1644-9] at No. 14, p. 22.) Mr. Smith had a prior history of non-compliance with Neurontin prescriptions. He had been prescribed Neurontin on May 5, 2003, by Dr. Paul McCombs, but it is undisputed that he did not fill, let alone take, this prescription. (McCombs progress note [MDL 1644-14]; Ruth Smith Dep. at 112:13-117:15; Maris Dep. at 536:11-537:20.) Likewise, Mr. Smith was given Neurontin samples in blister packs by Nurse Pamela Krancer, but it is undisputed that none of these blister packs were ever opened. (Cindy Smith-Charlton Dep. [MDL 1679-22] at 12:16-14:8, 79:4-81:21.) It is likewise undisputed that Mr. Smith did not take his last prescription of Neurontin as directed. Had he done so, he would have run out of pills by April 8, but the bottle was "full" at the time of his death on May 13, 2004. (Granacher Report [MDL 1644-12] at 6; Maris Dep. at 527:21-528:15, 540:5-18.)

During April and May of 2004, Mr. Smith's pain was "excruciating." (Trimble Dep. at 424:10-427:8.) He spent most of the day "lying around" because of pain. (Ruth Smith Dep. at 164:5-10, 165:22-166:2.) By this time, several surgeons had concluded that he was not a candidate for further surgical intervention. (Maris Dep. at 676:10-14, 679:4-680:1; Krancer Dep. [MDL 1644-10] at 24:7-18; Trimble Dep. at 398:5-399:4, 402:19-403:4.) In a handwritten note, Mr. Smith stated that his doctors had "nothing to offer him" besides steroid injections, medication, and physical therapy, none of which eased his pain. (Trimble Dep. at 445:9-17, 448:11-21, 450:2-24.)

Three days before committing suicide, Mr. Smith told Dr. Wood, his dentist and longtime family friend, that an end to his pain seemed "hopeless." (Wood Dep. at 15:24-16:3.) Mr. Smith told Dr. Wood that he had tried to get second opinions regarding his back, but that every physician he saw seemed to tune him out after hearing he already had surgery. (*Id.* at 16:4-22.) According to Mr. Smith, "[i]t was like they were all protecting each other." (*Id.*) Mr. Smith told Dr. Wood that he wished he never had back surgery and that "now I am almost useless," because

he could no longer do things he enjoyed, like cutting the grass. (*Id.* at 17:13-23, 19:22-24.) On May 13, 2004, Mr. Smith committed suicide. He left a suicide note that stated:

Pain has taken over my mind and body! I need back surgery, left and right rotator cuffs, right bicep torn, back surgery to correct pain in legs. Forgive me; I cannot go on like this. I cannot have my body, the temple of the Holy Spirit, cut on anymore. I have talked to God all night and he understands.

(Trimble Dep. at 497:4-498:4.)

### **SUMMARY JUDGMENT STANDARD**

Summary judgment should be granted when “there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law.” *Newman v. Fed. Express Corp.*, 266 F.3d 401, 404 (6th Cir. 2001); *see also* Fed. R. Civ. P. 56(c). Where, as here, the non-moving party has the burden of proof to establish her claim, the movant “need not support its motion with affidavits or other materials ‘negating’ the opponent’s claim.” *Moore v. Philip Morris Cos.*, 8 F.3d 335, 339 (6th Cir. 1993) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). Rather, ““the burden on the moving party may be discharged by ‘showing’ – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party’s case.”” *Id.* (quoting *Celotex Corp.*, 477 U.S. at 325); *accord Wixson v. Dowagiac Nursing Home*, 87 F.3d 164, 169 (6th Cir. 1996).

Accordingly, Pfizer is entitled to summary judgment if Plaintiff fails “to make a sufficient showing on an essential element of the case with respect to which [she] has the burden.” *Williams v. Ford Motor Co.*, 187 F.3d 533, 537 (6th Cir. 1999). Thus, the Sixth Circuit affirmed summary judgment in favor of a drug manufacturer based on the plaintiffs’ failure to demonstrate any material issue of fact regarding the essential element of causation.

Because [the defendant] does not bear the ultimate burden of persuasion on the causation issue, [it] need only point out the lack of a genuine issue regarding causation. . . . The reason for summary judgment was not the strength of the defendant’s proof, but the insufficiency of the plaintiffs’ proof.

*Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1071-72 (6th Cir. 1993).

Rule 56(c) requires the nonmovant to “go beyond the pleadings” and, by admissible evidence, “designate ‘specific facts showing that there is a genuine issue for trial.’” *Moore*, 8 F.3d at 339 (quoting *Celotex Corp.*, 477 U.S. at 324). If Plaintiff’s evidence on any element “is ‘merely colorable,’ or ‘not significantly probative,’ or not enough to lead a fair-minded jury to find for the non-moving party, the motion for summary judgment should be granted.” *Demoss v. Kretz*, No. 07-0405, 2009 WL 47142, at \*4 (M.D. Tenn. Jan. 7, 2009) (Trauger, J.) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-52 (1986)). Additionally, Plaintiff cannot satisfy her burden through “[m]ere conclusory and unsupported allegations, rooted in speculation,” *Bryant v. Kentucky*, 490 F.2d 1273, 1275 (6th Cir. 1974), or by pointing to “some metaphysical doubt as to the material facts.” *Moore*, 8 F.3d at 340; *see also Hedges v. R.M.S.I. Med. Dep’t Nurses*, No. 07-0284, 2009 WL 981979, at \*2 (M.D. Tenn. Apr. 13, 2009) (Trauger, J.) (“Conclusory allegations, speculation, and unsubstantiated assertions are not evidence and are not sufficient to defeat a well-supported motion for summary judgment.”).

## **ARGUMENT**

### **I. All Of Plaintiff’s Claims Fail For Lack Of Specific Causation**

Plaintiff has the burden of proving causation, an essential element of all product liability claims under Tennessee law. *See Pride v. BIC Corp.*, 54 F. Supp. 2d 757, 763 (E.D. Tenn. 1998), *aff’d*, 218 F.3d 566 (6th Cir. 2000). To establish causation, Plaintiff must first prove cause-in-fact. In this case, Plaintiff must prove that, but for Pfizer’s conduct, Mr. Smith would not have committed suicide. *See Mason ex rel. Mason v. Metro. Gov’t of Nashville*, 189 S.W.3d 217, 221 (Tenn. Ct. App. 2005). Plaintiff must also establish proximate causation; that is, that Pfizer’s conduct was a “substantial factor” in bringing about a foreseeable harm. *See Johnson v. Settle*, No. M1999-01237-COA-R3-CV, 2001 WL 585093, at \*6 (Tenn. Ct. App. June 1, 2001). Plaintiff can establish neither.

### A. Plaintiff Cannot Establish Cause In Fact

1. *Plaintiff cannot demonstrate that Mr. Smith consumed Neurontin shortly before his suicide*

To prove cause-in-fact in a prescription medication products liability case, a plaintiff must show that the injured person actually ingested the medication at issue. *See Porter v. Whitehall Labs., Inc.*, 791 F. Supp. 1335, 1340-41 (S.D. Ind. 1992), *aff'd*, 9 F.3d 607 (7th Cir. 1993); *Stanback v. Parke, Davis & Co.*, 502 F. Supp. 767, 771 (W.D. Va. 1980); *see also Barnes v. Kerr Corp.*, 418 F.3d 583, 589-90 (6th Cir. 2005) (affirming summary judgment to manufacturer where there was insufficient evidence that plaintiff was exposed to mercury from defendant's products). In this case, this requires that Plaintiff prove (1) how much, if any, Neurontin Mr. Smith took, (2) when he took it and (3) that he took it sufficiently close in time to his suicide to make a threshold showing of biological plausibility necessary to support causation.<sup>1</sup> Because Plaintiff cannot establish either that the decedent took Neurontin or when he took it, she cannot meet her burden of proof.

As Plaintiff's expert Dr. Maris has conceded, the relevant time period for Mr. Smith's ingestion of Neurontin is narrow: Because Neurontin has a half life of 5 to 7 hours,<sup>2</sup> there would be no appreciable Neurontin left in an individual's system within twenty-four hours after taking the drug. (Maris Dep. at 549:24-550:16.) Yet no one has testified that they observed Mr. Smith

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<sup>1</sup> Defendants do not concede that temporality is sufficient to establish causation. In fact, courts have repeatedly held that it is not. *See, e.g., McClain v. Metabolife Intern., Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005) ("[S]imply because a person takes drugs and then suffers an injury does not show causation. Drawing such a conclusion from temporal relationships leads to the blunder of the *post hoc ergo propter hoc* fallacy.") Indeed, "relying too heavily upon . . . the temporal proximity between the ingestion of a substance and the development of a subsequent illness" is one of the "'red flags' which should cause concern for the trial court, as gatekeeper, in admitting expert scientific . . . testimony." *Best v. Lowe's Home Centers, Inc.*, No. 04-cv-294, 2008 WL 2359986, at \*5-6, \*8 (E.D. Tenn. June 5, 2008) (citation omitted). However, the *absence* of any temporal connection between consumption of a drug and the alleged injury can *negate* causation. *See, e.g., In re Propulsid Prods. Liab. Litig.*, 261 F. Supp. 2d 603, 608-09, 617-18 (E.D. La. 2003) (granting summary judgment where plaintiff had stopped taking drug prior to alleged injury and there was no competent evidence that drug could cause prolonged effects).

<sup>2</sup> A medication's "half life" is the time it takes to be eliminated from blood plasma by one half of its strength. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 810 (30th ed. 2003) [MDL 1644-15].

take Neurontin within any of the four days – let alone twenty-four hours – leading up to his suicide, or even on any day in particular. (*Id.* at 529:14-531:4; *see also* Ruth Smith Dep. at 143:12-16.) Plaintiff's second expert, Dr. Trimble, likewise admits he does not know when Mr. Smith last took Neurontin prior to his death. (Trimble Dep. at 263:9-10.) Nor do Plaintiff's experts know how many Neurontin pills Mr. Smith may have ingested at any time. (Maris Dep. at 539:12-20.) Further, there is no toxicological evidence of any Neurontin in Mr. Smith's body at the time of his death. (Trimble Dep. at 268:19-269:13.) In sum, Plaintiff has produced no direct evidence that Mr. Smith ingested Neurontin during the critical time period.

Rather than producing evidence of Mr. Smith's alleged ingestion of Neurontin, Plaintiff relies on her belief that Mr. Smith must have taken his medications as prescribed because “that was just the way he did things.” (Ruth Smith Dep. at 143:2-16.)<sup>3</sup> But under the governing standard, Plaintiff's “[s]peculation, unsupported by facts in the record, is insufficient to create a genuine issue of material fact and falls short of what is required to survive summary judgment.” *Am. R. Serv. Co. v. Conrail Corp.*, 348 F.3d 565, 569 (6th Cir. 2003). More specifically, speculative testimony does not raise fact issues on the element of proximate cause.

Thus, in *Best v. Lowe's Home Centers, Inc.*, the court granted summary judgment dismissing the plaintiff's claim that exposure to pool chemicals had caused him to lose his sense of smell. *See Best*, 2008 WL 2359986 at \*9. The pool chemicals had allegedly splashed on plaintiff's face, and he went to the emergency room later that same day. *See id.* at \*1-2, \*4. Hospital records showed that plaintiff had denied inhaling the chemicals, and there was no competent evidence to the contrary. *See id.* at \*2. Based on the temporal proximity – less than one day – of plaintiff's exposure to the chemical and subsequent loss of smell, plaintiff's expert

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<sup>3</sup> Plaintiff also seeks to excuse the undisputed lack of evidence that Mr. Smith had Neurontin in his system by arguing that the fact “that no toxicology tests were conducted after Mr. Smith's violent suicide by gunshot that could demonstrate the presence of Neurontin in Mr. Smith's system would certainly not be unexpected.” (Pl. Mem. in Opp. to Summ. J. [MDL 1677] at 3.) But “unexpected” or not, Plaintiff's failure to present competent evidence raising fact issues for trial requires the entry of summary judgment. *See, e.g., Moore*, 8 F.3d at 339-40.

assumed without evidence that he “had to have had some exposure” via inhalation. *Id.* at \*3. Noting this conclusory assertion and other deficiencies in the expert’s methodology, the court granted summary judgment on the grounds that “the only proof Plaintiff has to offer is mere speculation that [the pool chemical] caused the loss of smell/anosmia injury.” *Id.* at \*9. *See also*, e.g., *Cooper v. Wyndham Vacation Resorts, Inc.*, 570 F. Supp. 2d 981, 986 (M.D. Tenn. 2008) (Trauger, J.) (“[A]n employee’s subjective belief or speculation that a causal connection exists will not defeat summary judgment.”). Tennessee law is in accord.<sup>4</sup>

The insufficiency of speculative testimony to withstand summary judgment is especially marked where, as here, the testimony comes from a party witness who has an obvious self-interest in the litigation. *See Cotton v. Wash. Metro. Area Transit Auth.*, No. CIV.A.01-0801, 2004 WL 473658 (D.D.C. Mar. 3, 2004) (“[I]t is settled that such ‘self-serving’ testimony, standing alone, will not protect the non-moving party from summary judgment.”) (internal quotation marks omitted); *Lehtonen v. Gateway Cos., Inc.*, No. 204-CV-0625-KJD-GWF, 2007 WL 2914649 at \*3 (D. Nev. Sept. 30, 2007) (“Uncorroborated and self-serving testimony, without more, will not create a ‘genuine issue’ of material fact precluding summary judgment.”) (internal quotation marks omitted). Plaintiff’s unsubstantiated “belief” is not a substitute for admissible evidence of proximate cause.

Additionally, summary judgment is proper because Plaintiff’s naked speculation is contrary to the evidence. *See Lassiter v. Neurological Surgeons, P.C.*, No. 3:07-1169, 2008 WL 5204060, at \*6 (M.D. Tenn. Dec. 11, 2008) (Trauger, J.) (granting summary judgment where

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<sup>4</sup> As the Tennessee Court of Appeals has noted, “[t]estimony of a speculative nature is not evidence, and does not establish proximate cause.” *Cupp v. Dixie Cycle Sales, Inc.*, No. 0IA01-9410-CV-00492, 1995 WL 247965, at \*5 (Tenn. Ct. App. Apr. 28, 1995) (citing *Lindsey v. Miami Dev. Corp.*, 689 S.W.2d 856, 861 (Tenn. 1985)); *see also Pointer v. Tenn. Equity Capital Corp.*, No. MI999-01934-COA-R3-CV, 2001 WL 1613893 (Tenn. Ct. App. Dec. 18, 2001) (“It is well settled that testimony which amounts to mere speculation is not evidence which establishes proximate cause.”) (internal quotation marks omitted); *Hodges*, 2009 WL 981979, at \*2 (speculative testimony does not bar summary judgment); *Moon v. Johnston*, 47 Tenn. App. 208, 218, 337 S.W.2d 464, 469 (Tenn. Ct. App. 1959) (affirming summary judgment, finding no evidence of proximate cause sufficient to raise fact issues and holding that a jury cannot be “permitted to speculate or guess as to the proximate cause of injury”).

plaintiff's argument was "based on the plaintiff's own speculation, speculation that is inconsistent with, or wholly unsupported by, the limited factual record before the court"). First, as noted above, Mr. Smith did not take his Neurontin as prescribed. Mr. Smith failed to fill an earlier prescription for Neurontin and failed to take even one pill from a blister pack given to him by his physician's nurse. (Ruth Smith Dep. at 112:13-117:15; Maris Dep. at 536:11-537:20; Cindy Smith-Charlton Dep. at 12:16-14:8, 79:4-81:21.) Had Mr. Smith been following directions, the one and only Neurontin prescription that he filled should have been empty by April 8, 2004, more than a month before his May 13, 2004 death. (Pls. Resp. to Defs. 1st Set of Interrogatories at No. 14, p. 22; Granacher Report. at 6.) Yet a bottle of Neurontin – which Dr. Maris described as "full" – was found on Mr. Smith's dresser after his death. (Maris Dep. at 527:21-528:15.) On this basis, even Dr. Maris conceded that Mr. Smith had to have "skipped a few doses." (*Id.* at 540:5-18.)

After Pfizer filed its motion for summary judgment in the MDL court, Plaintiff filed a supplemental declaration from Dr. Maris that takes us even further into the realm of speculation by suggesting that Neurontin could have a continuing influence on neurotransmitters even after it was eliminated from an individual's system, and thus could cause suicide days after it was ingested. (Maris Decl. [MDL 1673] ¶ 10.) Likewise, Professor Trimble speculates that "if you have a drug which acts on the brain and influences brain neurochemistry, you may well have an effect which by far outlasts the effect of the amount of the blood." (Trimble Dep. at 259:13-262:15.)<sup>5</sup> However, neither of these witnesses provided any support for this speculative opinion

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<sup>5</sup> Dr. Maris and Dr. Trimble expressed no such opinion in their expert reports. This alone requires that their speculative testimony be disregarded for purposes of this motion. *See, e.g., Brainard v. Am. Skandia Life Assurance Corp.*, 432 F.3d 655, 664 (6th Cir. 2005) (in granting summary judgment, district court properly disregarded new opinions in expert's affidavit that were not set forth in his report); *Matilla v. S. Ky. Rural Elec. Coop. Corp.*, 240 Fed. App'x 35, 42 (6th Cir. 2007) (affirming summary judgment and exclusion of expert's untimely new opinion). Both experts' conclusions are instead based on the groundless assumption that Mr. Smith took Neurontin up until the time of his death. (*See* Maris Report [MDL 1633-25] at 14; Trimble Report [MDL 1633-28] at 6.) Accordingly, neither Pfizer's *Daubert* motion nor Judge Saris's denial of that motion addressed the speculative opinion that Neurontin can have prolonged effects on brain chemistry even after leaving the system. Moreover, even where expert testimony is admissible, summary judgment is required where the expert's opinion leaves an "analytical gap" too wide to permit "reasonable inferences of causation." *Elkins*, 8 F.3d at 1071.

and neither explained how long Neurontin purportedly affects brain chemistry, what dose would be required, or whether Mr. Smith had taken a sufficient dose to cause any such prolonged effect. Indeed, Dr. Trimble admitted there was no literature supporting his suggestion that Neurontin can have any such prolonged effect. (*See id.*) This speculative testimony does not create an issue of material fact. *See Am. Road Serv. Co.*, 348 F.3d at 569; *Best*, 2008 WL 2359986 at \*9.

Plaintiff has argued that psychiatric opinion testimony regarding the factors that may have caused a person to commit suicide should be regarded as “soft” science subject to a more liberal standard of admissibility under *Daubert*. (Pl. Mem. in Opp. to Def. Mot. to Exclude Dr. Maris & Prof. Trimble [MDL 1671] at 4.) While Pfizer disputes this, opinion testimony regarding a drug’s supposedly prolonged effects on brain chemistry plainly falls within the “hard” sciences that are subject to *Daubert*’s reliability factors, *i.e.*, whether the theory can be and has been tested, whether it has been subject to peer review and publication; the known or potential rate of error; and the level of acceptance within the relevant discipline. *See Propulsid*, 261 F. Supp. 2d at 17. In *Propulsid*, the court granted summary judgment for the defendant drug manufacturer after determining that there was no reliable scientific basis for the plaintiffs’ experts’ opinion that the subject drug’s purported effect on “neurotransmitter[s]” could cause long-term cardiac problems that would persist after the drug had left the patient’s system. *Id.* at 608-09, 618. As the court explained:

[A]t best, Drs. Shell and Eckberg have discovered an event, but not a cause. They fail to identify the exact mechanism by which a person’s QT interval can become permanently prolonged well after that person has ceased taking Propulsid. Dr. Shell, in his testimony and reports, has admitted as much. Moreover, . . . Drs. Shell and Eckberg have been unable to show that such a condition exists with regularity and that it is caused by Propulsid. They have theories, but they have no proof to support those theories. Furthermore, their theories have not been tested or subjected to peer review and publication. They have no known or potential rate of error and there is presently no general acceptance of their methods in the scientific community. Under the prevailing logic of *Daubert* . . . , their testimony is unreliable.

*Id.* at 617.

In attempting to rely on her experts' *ipse dixit* speculations, Plaintiff fundamentally misapprehends her burden as the proponent of expert evidence and as the party opposing summary judgment. Pfizer does not have the burden of ““*negating*” Plaintiff's speculative notion that Neurontin can have a prolonged effect on neurotransmitters. *Moore*, 8 F.3d at 339 (emphasis in original) (citation omitted). Rather, Plaintiff has the burden of supporting that notion with competent, reliable scientific evidence, and her failure to do so requires the entry of summary judgment. *See Propulsid*, 261 F. Supp. 2d at 618; *Elkins*, 8 F.3d at 1071-72.

In sum, Plaintiff has not met her burden of coming forward with evidence to show product ingestion at any time temporally related to Mr. Smith's suicide. Plaintiff's “belief” that Mr. Smith took Neurontin during the days leading up to his death is unsupported by the evidence and insufficient to meet her burden of proof, because such speculative, self-serving testimony does not establish causation. Accordingly, all of Plaintiff's claims fail as a matter of law.

2. *Plaintiff has no evidence that Mr. Smith would not have been prescribed Neurontin had a suicide warning been included on the label*

Plaintiff is unable to raise triable issues of fact regarding causation for the additional reason that she has adduced no evidence that any additional or different warning would have changed any decision made by Mr. Smith's treating physician, Dr. Mackey, much less evidence that any different decision by Dr. Mackey would have averted Mr. Smith's suicide. Because all of Plaintiff's claims are premised on an alleged failure to provide adequate warnings about the risks of Neurontin, each is subject to the learned intermediary doctrine. *See, e.g., Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428-31 (Tenn. 1994) (granting summary judgment in favor of drug manufacturer after determining that the learned intermediary doctrine applied); *see also Harden v. Danek Med., Inc.*, 985 S.W.2d 449 (Tenn. Ct. App. 1999) (affirming grant of summary judgment to defendant, including negligence per se claim, on the basis of the learned intermediary doctrine). Under the learned intermediary doctrine, a manufacturer of prescription medications discharges its duty to warn “by providing the physician with adequate warnings of the risks associated with the use of its drug.” *Pittman*, 890 S.W.2d at 429. Thus, “[i]n order to

prove causation, the plaintiff must show that a proper warning [to the physician] would have changed the decision of the [physician] to prescribe the product.” *See Wyeth-Ayerst Lab. Co. v. Medrano*, 28 S.W.3d 87, 95 (Tex. Ct. App. 2000); *accord King v. Danek Med., Inc.*, 37 S.W. 3d 429, 453 (Tenn. Ct. App. 2001) (holding summary judgment proper where plaintiffs “failed to establish that, had additional warnings been given, the plaintiffs would not have sustained their injuries.”); *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992) (“[T]he plaintiff must establish that an adequate warning would have convinced the treating physician not to prescribe the product for the plaintiff.”). “[M]erely raising the possibility that [a physician] might have acted differently is not enough to satisfy Plaintiffs’ burden of proof on causation. . . . Plaintiff must provide ‘affirmative evidence’ that ‘an adequate warning to the prescribing physician would have altered the physician’s conduct.’” *Nix v. SmithKline Beecham Corp.*, No. CV-06-43-PHX-SMM, 2007 WL 2526402, at \*3 (D. Ariz. Sept. 5, 2007) (quoting *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001)) (emphasis omitted).

Though Plaintiff bears the burden of proof on this issue, she has failed to present evidence that Dr. Mackey<sup>6</sup> would not have prescribed Neurontin to Mr. Smith had a different warning been given. To the contrary, Dr. Mackey testified that he continues to prescribe Neurontin to this day. (Mackey Dep. [MDL 1644-8] at 83:24-84:13.) Moreover, when Plaintiff specifically asked Dr. Mackey whether he would have prescribed Neurontin to Mr. Smith based on the information he has today, Dr. Mackey testified only that he would prescribe Lyrica – another AED medication that was not available in 2004 – if Mr. Smith walked into his office on the date of his deposition. (Mackey Dep. at 92:16-93:2.)

Neither is Dr. Mackey’s testimony that, had he been warned of Neurontin’s alleged risk of suicide, he might have given additional warnings sufficient to withstand summary judgment. In a learned intermediary case, summary judgment is proper where the manufacturer

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<sup>6</sup> Because it is undisputed that the only Neurontin prescription Mr. Smith filled or took was written by Dr. Mackey, the prescribing decisions of Dr. McCombs and Nurse Krancer are irrelevant.

demonstrates that if an additional warning had been given, the intermediary would still have prescribed the medication. *See Medrano*, 28 S.W.3d at 95; *Thomas*, 949 F.2d at 812; *Nix*, 2007 WL 2526402, at \*3. A plaintiff may only withstand summary judgment in such circumstances by presenting evidence – of which there is none here – that the patient would nevertheless not have taken the medication. *See Vanderwerf v. SmithKlineBeecham Corp.*, 529 F. Supp. 2d 1294, 1313-14 & n.23 (D. Kan. 2008) (holding that testimony that physician would have monitored the patient more closely and warned the patient of risks did not bar summary judgment where plaintiff had no evidence that, given the additional monitoring and warning, the injury would have been avoided); *see also Spence v. Danek Med., Inc.*, No. 96C-1004, 1998 WL 665760, at \*4 (Tenn. Cir. Ct. June 17, 1998) (affirming the propriety of summary judgment where a plaintiff “failed to carry his burden of establishing that the drug would not have been prescribed had an adequate warning been provided”) (citing *Woulfe v. Eli Lilly & Co.*, 965 F. Supp. 1478 (E.D. Okla. 1997)). Here, it is undisputed that Mr. Smith was depressed and suicidal long before he ever allegedly took Neurontin. The suggestion that had Neurontin contained a suicide warning, Mr. Smith’s suicide could have been prevented through additional monitoring is pure speculation. Given his numerous risk factors, Mr. Smith should have been monitored for suicidal behavior regardless of whether he was taking Neurontin. “Speculation about how this tragedy might have been avoided is absolutely understandable and perhaps inevitable, but plaintiffs cannot escape summary judgment based on speculation.” *Vanderwerf*, 529 F. Supp. 2d at 1314.

Plaintiff previously argued that the MDL court should presume that Mr. Smith’s prescribers would have heeded an adequate warning based on the heeding presumption discussed in comment j to Section 402A of the Restatement (Second) of Torts. (Pl. Mem. in Opp. to Summ. J. [MDL 1677] at 14-15.) This argument must be rejected because Tennessee courts have not adopted or applied the heeding presumption. Moreover, even if the heeding presumption applied (which it does not), it would not satisfy Plaintiff’s burden at trial or in response to this motion.<sup>7</sup>

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<sup>7</sup> Even where the heeding presumption applies, “heed” in this context means only that the learned intermediary would have incorporated the ‘additional’ risk into his decisional calculus. The burden (*cont’d*)

In sum, no authority permits Plaintiff to survive summary judgment and proceed to trial in a prescription drug/wrongful death case where the record contains (i) physical evidence that the decedent did not take the medication as prescribed, in the form of a “full” pill bottle and unopened blister packages at the death scene weeks after prescribed quantities would have been exhausted, (ii) admissions by the plaintiff’s experts that the decedent skipped multiple doses, (iii) a record devoid of any percipient witness’s observation of any ingestion of the medication at any time, (iv) no toxicological evidence of any of the subject medication in the decedent’s body, (v) undisputed evidence that the medication clears from the body within hours of ingestion, and (vi) no admissible scientific evidence that the medication produces any persistent changes in the body, much less that any such persistent changes cause suicide.

#### **B. Plaintiff Cannot Establish Proximate Causation**

“Tennessee courts have . . . ‘consistently recognized’ that suicide properly constitutes an independent intervening cause in most wrongful death actions.” *MacDermid v. Discover Fin. Servs.*, 488 F.3d 721, 736 (6th Cir. 2007) (quoting *Rains v. Bend of the River*, 124 S.W.3d 580, 593 (Tenn. Ct. App. 2003)). As a corollary of the proximate cause analysis, the doctrine of independent intervening cause is meant to establish a “boundary of legal liability.” See *Rains*, 124 S.W.3d at 592 (citations omitted). Recognizing that suicide is a willful act, Tennessee has long held that “[a]n act of suicide resulting from a moderately intelligent power of choice, even though the choice is determined by a disordered mind, should be deemed a new and independent . . . cause of the death that immediately ensues.” *Jones v. Stewart*, 183 Tenn. 176, 179, 191 S.W.2d 439, 440 (Tenn. 1946). As a result, courts applying Tennessee law have

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remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician’s decision to prescribe the product for the plaintiff.” *Thomas*, 949 F.2d at 814 (footnotes omitted); see also *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1021 (10th Cir. 2001) (explaining that the prescribing physician only “heed[s]” warnings in the sense of considering them while deciding how to prescribe the product and whether or not to tell the patient about the risk and that it is unrealistic to presume physicians would “heed” any warning either in the sense of never using the product or that they would automatically tell every patient about every risk).

repeatedly granted summary judgment in cases involving suicide. *See, e.g., Rains*, 124 S.W.3d at 596; *MacDermid*, 488 F.3d at 736. Tennessee courts further recognize that proximate cause often depends upon legal and policy questions that can be resolved as a matter of law by courts.

While proximate cause is to some extent associated with the nature and degree of the connection in fact between the defendant's acts and the events of which the plaintiff complains, often to a greater extent, however, the legal limitation on the scope of liability is associated with policy – “with our more or less inadequately expressed ideas of what justice demands or of what is administratively possible and convenient.”

*Bain v. Wells*, 936 S.W.2d 618, 625 (Tenn. 1997) (reversing denial of summary judgment; plaintiff could not recover on emotional distress claim absent evidence of actual exposure to HIV) (quoting Prosser & Keeton, *The Law of Torts* § 41, p. 264 (5th ed. 1984)).<sup>8</sup> In this case, Tennessee law recognizes, as a matter of public policy, that someone should not be held liable for the volitional act of another person. *See Jones*, 183 Tenn. at 179, 191 S.W.2d at 440.

There are only three exceptions to the rule that suicide breaks the chain of causation, only one of which is even arguably applicable here: “where defendant’s negligence causes ‘delirium’ or ‘insanity’ that results in self-destructive acts.” *MacDermid*, 488 F.3d at 736; *accord Rains*, 124 S.W.3d at 593-94.<sup>9</sup> However, the delirium/insanity exception is “extremely limited in application,” and there is not “a single [Tennessee] case in which this particular exception was applied in a plaintiff’s favor.” *Id.* at 736-37. Tellingly, this exception has been tested – **and rejected** – in cases involving conduct far more egregious and direct than that alleged in this case.

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<sup>8</sup> *See also, e.g., Snyder v. LTG Lufttechnische GmbH*, 955 S.W.2d 252, n.6 (Tenn. 1997) (“Proximate or legal cause is a policy decision made by the legislature or the courts to deny liability for otherwise actionable conduct based on considerations of logic, common sense, policy, precedent and ‘our more or less inadequately expressed ideas of what justice demands or of what is administratively possible and convenient.’”) (citation omitted); *Kilpatrick v. Bryant*, 868 S.W.2d 594, 598 (Tenn. 1993) (“Fixing this boundary of liability is the purpose underlying the element of proximate cause.”).

<sup>9</sup> The other two exceptions are “where defendant is the decedent’s custodian, and defendant knows or has reason to know that the decedent might engage in self-destructive acts” and “where defendant and decedent have a legally recognized ‘special relationship,’ such as physician-patient relationship, and defendant knows or has reason to know that the decedent might engage in self-destructive acts.” *See MacDermid*, 488 F.3d at 736 (rejecting applicability of these exceptions).

For instance, in *Eckerd's, Inc. v. McGhee*, 19 Tenn. App. 277, 86 S.W.2d 570 (Tenn. Ct. App. 1935), the court reversed a jury verdict for a minor plaintiff who sued a pharmacy for wrongfully selling her poison with which she attempted suicide. The court held that the minor's actions were an independent intervening cause because there was no "reasonable basis for an inference that [the plaintiff] was insane or mentally incompetent to the extent that she did not know and comprehend the full import and consequences of what she was doing at the time in question." *Id.* at 289, 86 S.W. 2d at 577. More recently, the Tennessee Court of Appeals in *Rains* reversed a denial of summary judgment to a retailer who had wrongfully sold ammunition to an underage boy who used the ammunition to commit suicide. *See Rains*, 124 S.W.3d at 584. The court held that the boy's actions were not sufficiently foreseeable to overcome the presumption of independent intervening cause. *Id.* at 594-95.

Similarly, the delirium/insanity exception did not apply in a case where the defendant, Montesi, was having an extramarital affair with the decedent, Mrs. Lancaster, and had inflicted sadistic punishment on her, including breaking her leg, burning her with a cigarette, and beating her repeatedly. *Lancaster v. Montesi*, 216 Tenn. 50, 53, 390 S.W.2d 217, 219 (Tenn. 1965). Mrs. Lancaster had even attempted suicide in Montesi's presence. *Id.* Ultimately, Mrs. Lancaster killed herself, leaving a note saying, "Ma Ma, I'm sorry. Louis [Montesi] has beat me enough." *Id.* Nevertheless, the Tennessee Supreme Court held that the action should be dismissed, because even though plaintiffs alleged that Mrs. Lancaster was "'bereft of reason,' it [could not] be said that she did not know and understand the nature of her act," which was an independent intervening cause relieving Montesi of liability. *Id.* at 60, 390 S.W.2d at 222.<sup>10</sup>

In the recent *MacDermid* opinion, which involved allegations that the credit card issuer had inflicted emotional distress on the decedent resulting in her suicide, the Sixth Circuit

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<sup>10</sup> See also *Potts v. First Peoples Bank of Jefferson County*, No. 03A01-9303-CV-00116, 1993 WL 276858, at \*1-3 (Tenn. Ct. App. July 22, 1993) (rejecting application of delirium/insanity exception against defendant bank where decedent committed suicide after his daughter forged his signature to guarantee loans and bank threatened to take his house).

concluded that “[i]f the facts of [*Lancaster*] do not fit the delirium/insanity exception . . . then neither do the facts in the instant case.” 488 F.3d at 738. So here also. If Montesi’s repeated sadistic punishment of Mrs. Lancaster, notwithstanding his actual knowledge of her past suicidal ideation, was insufficient to trigger the delirium/insanity exception, then neither is Pfizer’s alleged conduct here: marketing an FDA-approved medication claimed to cause suicidal ideation – a claim as to which there is considerable, legitimate dispute. Indeed, none of Plaintiff’s experts have even suggested that Mr. Smith’s suicide did not spring from even a “moderately intelligent power of choice.” *Jones*, 183 Tenn. at 179, 191 S.W.2d at 440. To the contrary, the undisputed facts clearly confirm that Mr. Smith understood the nature of his act, given (i) his lucid, grammatically correct suicide note, which clearly articulated both his reasons and his desire for forgiveness, (ii) the fact that he locked the door and put plastic on the bed, and (iii) his remark about suicide a year before ingesting any Neurontin. There is thus no evidence sufficient to overcome the legal presumption that his suicide was an independent intervening cause.

## **II. Plaintiff’s Implied Warranty Claims Fail As A Matter Of Law**

Plaintiff’s claims for breach of the implied warranty of merchantability fail not only because Plaintiff cannot prove causation, as set forth above, but also for additional reasons specific to those claims. First, Plaintiff cannot recover under a theory of implied warranty because she has failed to provide the required pre-suit notice. Under Tennessee law, a plaintiff must “within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy.” Tenn. Code Ann. § 47-2-607(3)(a) (emphasis added). The requirement of pre-suit notice is grounded in the policy of giving the seller the opportunity to settle the dispute prior to litigation. See UCC § 2-607 cmt. 4 (2009) (“[N]otification . . . opens the way for normal settlement through negotiation.”); *see also Parker v. Bell Ford, Inc.*, 425 So.2d 1101, 1103 (Ala. 1983) (pre-suit notice allows vendor to “suggest opportunities for cure”); *accord Zeigler v. Sony Corp. of Am.*, 849 A.2d 19, 24 (Conn. Super. Ct. 2004). Yet Plaintiff never gave Pfizer that opportunity, as it is undisputed that she did not provide Pfizer with any notice of breach before filing this suit. She has thus failed to provide

“reasonable notice” as required by Tennessee law and is barred from any remedy in implied warranty. *See Friedman v. Georgia Showcase Co.*, 27 Tenn. App. 574, 577-82, 183 S.W.2d 9, 11-12 (Tenn. Ct. App. 1944) (where buyer failed to give notice until lawsuit was filed, buyer was barred from recovering damages from alleged breach).

Second, Plaintiff cannot prevail on her claim for breach of the implied warranty of fitness, because she cannot prove that Mr. Smith or Dr. Mackey actually relied on Pfizer’s skill and judgment in purchasing Neurontin. Tenn. Code Ann. § 47-2-315; see also UCC § 2-315, cmt. 1 (“The buyer, of course must actually be relying on the seller.”); *Travelers Indem. Co. v. Indus. Paper & Packaging Corp.*, No. 3:02-CV-491, 2006 WL 3864857, at \*10 (E.D. Tenn. Dec. 18, 2006). Although Plaintiff pleads that Mr. Smith “relied upon the aforesaid express and implied warranties” (Pl. Am. Compl. [MDL 1209] ¶ 163), she has produced no evidence of any communication from Pfizer on which Mr. Smith allegedly relied. Plaintiff likewise has no evidence that Dr. Mackey relied on any alleged warranties. Accordingly, summary judgment should be granted on Plaintiff’s implied warranty of fitness claim. *See, e.g., Baker v. Promark Prods. West, Inc.*, 692 S.W.2d 844, 849 (Tenn. 1985) (affirming grant of summary judgment where plaintiff did not rely on defendant’s skill or judgment to furnish suitable goods).

### **III. Plaintiff’s Fraudulent Concealment Claims Fail For Additional Reasons**

Pfizer is entitled to summary judgment as to the little that remains of Plaintiff’s fraud claims. Because the MDL court dismissed Plaintiff’s claims of affirmative fraud, only Plaintiff’s claims of fraudulent concealment remain in this action. *In re Neurontin Mktg.*, [05-11515 Dkt. No. 10] at 2. Moreover, the MDL court also ruled that Plaintiff could not assert this fraudulent concealment claim “premised on . . . fraudulent omissions in the national advertising and marketing campaign,” as this would require an untenable fraud-on-the-market theory of reliance. *In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 618 F. Supp. 2d 96, 114 (D. Mass. 2009). The MDL court thus reserved for this Court only the state-law issues in the remaining sliver of Plaintiff’s fraudulent concealment claim. Yet this claim also fails under Tennessee law.

The Tennessee Supreme Court has held that a party commits fraudulent concealment only when it “has a duty to disclose a known fact or condition [but] fails to do so, and another party reasonably relies upon the resulting misrepresentation, thereby suffering injury.” *Chrisman v. Hill Home Dev.*, 978 S.W.2d 535, 538-39 (Tenn. 1998). Under Tennessee law, “[t]he duty to disclose arises in three distinct circumstances: (1) where there is a previous definite fiduciary relation between the parties, (2) where it appears one or each of the parties to the contract expressly reposes a trust and confidence in the other, and (3) where the contract or transaction is intrinsically fiduciary and calls for perfect good faith.” *Shah v. Racetrac Petroleum Co.*, 338 F.3d 557, 571 (6th Cir. 2003) (internal quotation marks omitted); *accord Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 721 (E.D. Tenn. 2001). “Clearly, none of those circumstances are present here,” and Plaintiff is thus unable to establish a duty. *Morgan*, 165 F. Supp. at 722 (granting summary judgment to beryllium manufacturer on fraudulent concealment claims for lack of duty to disclose); *see also McConkey v. McGhan Med. Corp.*, 144 F. Supp. 2d 958, 965-66 (E.D. Tenn. 2000) (granting summary judgment to breast implant manufacturer on fraud claims for lack of duty to disclose).<sup>11</sup> Absent a duty to disclose, of which there is no evidence here, Plaintiff cannot make out an essential element of her fraudulent concealment claims, and Pfizer is entitled to judgment as a matter of law.<sup>12</sup>

## **CONCLUSION**

For the foregoing reasons, this Court should grant Pfizer’s motion for summary judgment, dismissing Plaintiff’s claims in their entirety.

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<sup>11</sup> Neither can Plaintiff base her state-law fraudulent concealment claim on a federal duty to disclose information to the FDA, because such claims are barred by *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001), which held that fraud-on-the-FDA claims are preempted.

<sup>12</sup> Although Pfizer has a duty to warn of risks posed by its products, *see McConkey*, 144 F. Supp. 2d at 964, this duty arises not under a fraudulent concealment theory, but under a products liability theory of failure to warn. *See id.* at 964-66 (rejecting liability under fraudulent concealment); *Shah*, 338 F.3d at 571-72 (duty to disclose in fraudulent concealment claims limited to three duties classically recognized under Tennessee law).

Dated: December 4, 2009

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this the 4<sup>h</sup> day of December, 2009, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system.

/s/ Gerald D. Neenan